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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/054,354	LAWTON ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *2/04* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL ACTION

1. This Office Action is responsive to Applicant's amendment and response filed February 24, 2004. Claims 1 and 3-6 have been amended. Clams 7-8 have been added. The Declaration filed under 37 C.F.R. 1.132 (declaration of Dr. Chandrashekar) is acknowledged but is insufficient to overcome the art rejection. Applicant's submission of Bowie et al *(Science 247:1306-1310 (1990))* is acknowledged.

2. The text of those sections of the Title 35, U.S. code not included in this action can be found in the prior Office Action.

Objections and Rejections Withdrawn

3. In view of Applicant's amendment and response the following rejections are withdrawn:

a) Objection to the specification, page 2, paragraph 1.

b) Objection to the specification, page 2, paragraph 2.

c) Objection to the claims 4-6, page 2, paragraph 3.

d) Objection to the claims 5-6, page 2, paragraph 4.

e) rejection of claim 3 under 35 U.S.C. 112, second paragraph, page 8, paragraph 8.

f) rejection of claim 5 under 35 U.S.C. 112, second paragraph, page 9, paragraph 9.

g) rejection of claim 5 under 35 U.S.C. 112, second paragraph, page 9, paragraph 10.

Rejections Maintained

4. The rejection under 35 U.S.C. 112, first paragraph (written description) maintained for claims 1-6 and newly submitted claims 7-8 for the reasons set forth in pages 3-5 paragraph 6 of the previous Office Action.

The rejection was on the grounds that the claims are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. *This is a written description rejection.*

The specification broadly describes as a part of the invention a composition and an article of manufacture comprising the isolated polypeptide of SEQ ID No: 1 and variants thereof. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states " that naturally occurring variants and non-naturally occurring variants are included in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). Applicant has broadly described the invention as embracing any substitution, insertion or deletion change of amino acids throughout the length of the polypeptide sequence. Variants of SEQ ID No:1 correspond to sequences from other species, mutated sequences, allelic variants, splice variants, sequences that have a variant degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 U.S.C. 112, first, paragraph. The specification provides insufficient written description to support the genus encompassed by the claim. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO:1, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Therefore, only SEQ ID NO: 1 but not the full breadth of the claim (or none of the sequences encompassed by the claim) meets the written description provision of 35

USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicant urges that claims 1 and 3 have been amended to clarify the claimed variants are amino acid substitution variants of SEQ ID NO:1 that specifically bind to an anti-*Ehrlichia* antibody. Applicant urges that the specification teaches that amino acid substitution variants of the invention can be made. Applicant urges that the specification provides detailed guidance on how to construct variants of SEQ ID NO:1. Applicant urges that the partial structure of the claimed variants are known, i.e. sequence that have at least 85% identity to SEQ ID NO:1 and therefore, the variants have about 17 amino acids in common with the 20 amino acid long SEQ ID NO:1. Applicant urges that physical properties and functional characteristics of the variants are known. Applicant urges that Bowie et al, *Science*, 247:1306 (1990) teaches methods of construction of variants and the tolerance of the protein sequences to substitution. Applicant urges that the specification teaches that the polypeptides of the invention "specifically bind to anti-*Ehrlichia* antibodies". Applicant urges that written description standard requires that one skilled in the art must recognize that the Applicant was in possession of the claimed genus, that is variants of SEQ ID NO:1. Applicant urges that one species can adequately support a genus. Applicant urges that one skilled in the art would recognize that Applicant was in possession of the genus in view of the species disclosed because the partial structure, physical and/or chemical properties, functional

characteristics and methods of making the claimed variants is disclosed in the specification.

Applicant's arguments filed February 23, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show that the specification is enabled for the full scope of the claims and therefore does not meet the written description requirement as set forth in 35 U.S.C. 112, first paragraph. Applicant has not shown enablement for variants of SEQ ID No.1. The specification discloses only species SEQ ID NO: 1 within the genus of the claimed invention. The specification proposes to discover other members of the genus by using a sequence comparison algorithm (pages 6-7). The specification also states " that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). The specification discloses only SEQ ID NO:1 which corresponds to an isolated polypeptide of *Enrlichia*. The specification does not provide enablement for the full scope of the claimed invention. Applicant has provided no structural description accompanying the variant language recited in the claims. While use of BLAST and other sequence comparison tools are known, it is not routine in the art to screen for multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining similar activity are limited in any protein and the result of such modifications is unpredictable based on the instant disclosure. However, the claims are directed to a composition of matter consisting essentially of SEQ ID

NO:1 or an amino acid substitution variant thereof that specifically binds to an anti-*Ehrlichia* antibodies which encompasses sequences from other species, mutated sequences, splice variants, sequences that have a recited degree of identity (similarity, homology), and so forth. The general knowledge of the art concerning species does not provide any indication of how the structure of a limited number of other species is representative of unknown species. The nature of the species within a genus are variant structures. The requirement under the U.S.C. 35 112, first written description is that the Applicant is possession of the claimed invention. How can one of skilled in the art conclude that Applicant was in possession of the claimed invention if there is no structural description for an amino acid substitution variant of SEQ ID NO:1 disclosed in the instant specification? One skilled in the art would concluded that Applicants were not in possession of the claimed genus polypeptides.

To address Applicant's comments regarding Bowie et al, it should be noted that the specification and Bowie et al merely teaches that amino acids modifications can be made. It should be noted that Bowie et al discloses that problems exist with the prediction structure and function from a sequence (page 1).

5. The rejection under 35 U.S.C. 112, first paragraph (enablement) is maintained for claims 1-6 and newly submitted claims 7-8 for the reasons set forth in pages 5-7, paragraph 7 of the previous Office Action.

The rejection was on the grounds that the claims rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a composition and an article of manufacture that comprise SEQ ID No:2, does not reasonably provide enablement for a composition or an article of manufacture that comprise variants of SEQ ID. No:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claims 1-6 are directed to a composition and a article of manufacture comprising the isolated polypeptides of SEQ ID NO: 2 and variants thereof.

The specification is enabling only for the polypeptides of SEQ ID NO:2 as disclosed in the specification. The specification states that "variants in which amino acids of the polypeptides of the invention are substituted, deleted or added in any combination are contemplated by the invention". The specification also states " that naturally occurring variants and non-naturally occurring variants are included in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). The specification teaches that there are many tolerable and conservative amino acid substitutions which can be made that are not critical to protein function (pages 7-9). There is no guidance provided as to which amino acids can be added, deleted or substituted and the polypeptide would retain its biological function. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of polypeptides broadly encompassed by the claims and the claims broadly encompass a significant number of inoperative species. Since the amino acid sequence of the polypeptide determines its structural and functional properties, predictability of which changes can be tolerated in a polypeptide's amino acid sequence and still retain similar activity/utility requires a knowledge with regard to which amino acids in the polypeptide's sequence, if any, are tolerant of modification and which are conserved (i.e. expected intolerant to modification) and detailed knowledge of the ways in which the polypeptide's structure relates to function. However, the problem of the prediction of polypeptide structure from mere sequence data of a single polypeptide and in turn utilizing predicted structural determinations to ascertain functional aspects of the polypeptide and finally what changes can be tolerated with respect thereto is extremely complex and outside of the realm of routine experimentation.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen multiple substitutions or multiple modifications of other types and the positions within the polypeptide's sequence where amino acid modifications can be

made with a reasonable expectation of success in obtaining similar activity are limited in any polypeptide and the result of such modifications is unpredictable based on the instant disclosure. One skilled in the art would expect any tolerance to modifications, e.g., multiple substitutions. The sequence of some polypeptides is highly conserved and one skilled in the art would not expect tolerance to any amino acid modification in such polypeptides.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the above test to the facts of record, it is determined that 1) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 2) insufficient direction or guidance is presented in the specification with respect to selecting other antigens having claimed functional features, 3) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level). One of skill in the art would require guidance, in order to make or use polypeptides that are variants of SEQ ID NO: 2 in a manner reasonable in correlation with the scope of the claims. Without proper guidance, the experimentation is undue.

Applicant urges that claims 1 and 3 have been amended to clarify the claimed variants are amino acid substitution variants of SEQ ID NO:1 that specifically bind to an anti-*Ehrlichia* antibody. Applicant urges that the specification teaches that amino acid substitution variants of the invention can be for example, phenotypically silent amino acid substitutions and/or conservative amino acid substitutions. Applicant urges that the specification provides detailed guidance on how to construct variants of SEQ ID NO: 1 (see Bowie et al). Applicant urges that a structural description of the claimed variants is provided by the specification. Applicant urges that phenotypically silent or conservative amino acid substitution variants that have at least 85% identity and specifically bind to an anti-*Ehrlichia* antibody. Applicant urges that since SEQ ID NO:1 is about 20 about 20 amino acids long, an amino acid substitution variant has only 3 amino acid

substitutions at the most. Applicant urges that one skilled in the art could design, make and test phenotypically silent and conservative amino acid variants of SEQ ID NO:1. Applicant urges that the test of enablement is not merely quantitative since a considerable amount of experimentation is permissible, if it is merely routine or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. Applicant urges that the specification teaches that making and testing the polypeptides and variants of the invention are trivial as outlined in the specification. Applicant urges that a reasonable expectation of success in not a standard for enablement. Applicant urges that one in the art would expect to identity the claimed variants using only routine experimentation.

Applicant's arguments filed February 23, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that Applicant has not shown enablement for variants of SEQ ID No.1. The specification discloses only species SEQ ID NO: 2 within the genus of the claimed invention. The specification proposes to discover other members of the genus by using a sequence comparison algorithm (pages 6-7). The specification also states " that naturally occurring variants and non-naturally occurring variants are include in the invention and may be produced by mutagenesis techniques or by direct synthesis" (page 7). There is no description of the mutational sites that exist in nature. The specification discloses only SEQ ID No:1 which corresponds to an isolated protein of *Ehrlichia*. The specification fails to provide guidance as to which amino acids can be changed and the polypeptides still retain their claimed biological function. The nature of the species within a genus are variant

structures. In the present state of the art, the structure of a limited number of species does not provide guidance to the structure of others and is insufficient to support the claimed invention. To address Applicant's comment regarding "a reasonable expectation of success is not required under 35 U.S.C. 112, first paragraph", it should be noted that the 35 U.S.C. 112 first paragraph statue requires that Applicants teach how to "make and use" the claimed invention not how to "find" variants of SEQ ID NO:1 that specifically bind to an anti-*Ehrlichia* antibody". A structural description is required. One skilled in the art would require guidance in order to make and use the claimed composition of matter or article of manufacture comprising phenotypically silent amino acid substitution variants of SEQ ID NO:1 commensurate in scope with the claims. Therefore, one skilled in the art would have to be successful in producing polypeptides that are variants of SEQ ID NO:1 which have a defined structure to satisfy the enablement requirement under 35 U.S.C. 112, first paragraph.

6. The rejection under 35 U.S.C. 102(a) is maintained for claims 1-3 for the reasons set forth on pages 9-10, paragraph 11 of the previous Office Action.

The rejection was on the grounds that Rikihisa et al teach diagnostic tools for veterinary and human use which are used for serodiagnosing ehrlichiosis in mammals (see the Abstract). Rikihisa et al teach compositions of matter and articles of manufacture which such as a column, plastic dish, matrix or membrane preferably nitrocellulose containing an isolated outer membrane of *E. chaffeensis or E. canis.* used in a diagnostic method of detecting antibodies to the *E. chaffeensis or E. canis* in a sample of bodily fluid from a patient (page 11). Which meets the claim limitation that "the article of manufacture comprises packaging material and contained within the packaging material the polypeptide shown in SEQ ID NO:1". Rikihisa et al teach the isolated polypeptide shown in SEQ ID NO:1, (see Figure 21B). Therefore, the composition of matter and article of manufacture of Rikihisa et al appears to be the same as the claimed invention.

Applicant urges that under 102, a claim is anticipated only if each and every element as set forth in the claim is found in a single art reference. Applicant urges that a certain characteristic may occur or be present in a prior art reference is not sufficient to establish inherency of that characteristic. Applicant urges that the Office has not provided a basis in fact and/or technical reasoning to show that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art. Applicant urges that Rikihisa et al do no teach or suggest the used of polypeptide fragments in devices an in particular do not teach or suggest the particular fragment shown in SEQ ID NO:1. and amino acid substitution variants thereof. Applicant urges that the Office has not provided basis that the whole recombinant protein antigens in Rikihisa et al would be fragmented in any way. Applicant urges that the claimed compositions of matter provide greater sensitivity than the reagents taught in Rikihisa et al (see the declaration of Dr. Chandrashekar).

Applicant's arguments filed February 23, 2004 have been fully considered but they are not persuasive. It is the Examiner's position that there is nothing on the record to show that the claimed composition and article of manufacture differs from the composition and article of manufacture of the prior art. The claims are drawn to composition and article of manufacture consisting essentially of an isolated polypeptide shown in SEQ ID NO:1 or an amino acid substitution variant thereof. Rikihisa et al teach an antigen (i.e. isolated polypeptide) used in a Western immunoblot analysis and a dot blot analysis to detect the presence of antibody to *E. canis* (page 17). The

claimed invention encompass variants of SEQ ID NO: 1, therefore one skilled in the art could reasonably conclude that the *E. canis* polypeptides of the prior art are variants of SEQ ID NO:1 since Rikihisa et al teach that the invention embraces non-naturally occurring allelic forms or derivatives of the outer membrane proteins (i.e. P30) (page 10) and Rikihisa et al teach the isolated polypeptide shown in Figure 21B. Applicant has provided no side-by-side comparison to show that the claimed polypeptide differs from the *E. canis* polypeptides of the prior art. It should be noted that the claim recites "consisting essentially of" which is open claim language which suggest that other components that do not cause a negative effect on the compositions of matter can be present in the claimed invention.

In regards to Applicant's referral to the Declaration filled under 37 C.F.R. 1.132 (declaration of Dr. Chandrashekar) to point out that the compositions of matter of the claimed invention are more sensitive than that of the prior art, it should be noted that there are not limitations in the claims requiring that the compositions of matter require any particular level sensitivity. To address Applicant's comments regarding inherency, there is no limitation in the claims nor is this issue addressed in the Examiner's rejection. The prior art teaches composition and article of manufacture consisting essentially of an amino acid substitution variants of SEQ ID NO:1. Therefore, Rikihisa et al anticipate the claimed invention.

7. The rejection under 35 U.S.C. 103(a) is maintained for claims 1-6 for the reasons set forth on pages 10-14, paragraph 12 of the previous Office Action.

The rejection was on the grounds that Rikihisa et al teach diagnostic tools for veterinary and human use which are used for serodiagnosing ehrlichiosis in mammals (see the Abstract). Rikihisa et al teach compositions of matter and articles of manufacture which such as a column, plastic dish, matrix or membrane preferably nitrocellulose containing an isolated outer membrane proteins of *E. chaffeensis or E. canis*. used in a diagnostic method of detecting antibodies to the *E. chaffeensis or E. canis* in a sample of bodily fluid from a patient (page 11). Rikihisa et al teach the isolated polypeptide shown in SEQ ID NO:1, (see Figure 21B).

Rikihisa et al do not teach the use of a label indicates that the polypeptide can be used for the identification of *Ehrlichia* infection in a mammal.

Waner et al teaches a label that indicates the use of the composition of matter or the article of manufacture (page 241, Figure 1).

It would be *prima facie* obvious at the time the invention was made to add label as taught by Waner et al to the composition of matter or article of manufacture of Rikihisa et al because it is well known in the art to include packing material and a label to indicate the intended use of the composition of matter or article of manufacture.

The printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, composition, or article of manufacture, absent a functional relationship between the label or package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. In the opinion text of In re Haller, it is stated that: Whether the statement of intended use appears merely in the claim or in a label on the product is immaterial so far as the question of patentability is concerned...In accordance with the patent statutes, an article or composition of matter, in order to patentable, must not only be useful and involve invention, but must also be *new*. If there is no novelty in an article or composition itself, then a patent cannot be properly granted on the article or composition, regardless of the use for which it is intended. The difficulty is not that there can never be invention in discovering a new process involving the use of an old article, but that the statues make no provision for patenting of an article or composition which is not, in and of itself, new.

Also see In re Venezia 189 USPQ 49 (CCPA 1976), where kits are drawn to the structural attributes of interrelated component parts and not to activities that may or may not occur. Further, In re Miller 164 USPQ 46 (CCPA 1969) and In re Gulak (CA FC)217 USPQ 401 relate to a mathematical device and to a measuring cup respectively. In each of these cases, the printed matter is considered a patentable distinction because the function of the device depends upon the printed matter itself which is a part of the substrate; without the printed indicia or numbers, the substrates lose their function. Such is not the case with the instantly claimed articles. The

polypeptides of the claimed articles remain fully functional absent the labeling or printed instructions for use.

It is further noted that the written material in the instructions is not considered to be within the statutory classes and does not carry patentable weight. See MPEP 706.03(a).

Thus the instructions for use included in composition of matter and article of manufacture constitute an "intended use" for that composition of matter or article of manufacture. Intended use does not impart patentable weight to a product. See MPEP 2111.03: Intended use recitations and other types of functional language cannot be entirely disregarded. However, in apparatus, article, and composition claims, intended use must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967); In re Otto, 312 F.2d 937, 938, 136 USPQ 458, 459 (CCPA 1963)

In the instant case, the claims are drawn to a composition of matter and an article of manufacture which comprises an isolated polypeptide shown in SEQ ID NO:1, and a label that indicates the use of the composition of matter or article of manufacture. The intended use which is recited on the label or package insert lacks a function relationship to the polypeptide because the insert or label does not physically or chemically affect the chemical nature of the polypeptide within the composition of matter or article of manufacture, and furthermore, the polypeptide can still be used by the skilled artisan for other purposes. Therefore the polypeptide which are comprised within the composition of matter and the article of manufacture are unpatentable over the prior art polypeptide, because they function equally effectively with or without the labeling, and accordingly *no functional relationship exists between the instructions for use and the polypeptide.*

Thus the claims are addressed as being drawn to a composition of matter and an article of manufacture comprising an polypeptide and a label that indicates that the polypeptide can be used for the identification of *Ehrlichia* infection in a mammal, the instructions on the label bearing no patentable weight with regard to double patenting, 102, and 103 rejections.

Applicant urges that Rikihisa et al does not teach or suggest isolated polypeptides consisting essentially of SEQ ID NO:1. Applicant urges that Waner et al do not correct the defects of the primary reference by teaching the elements missing from Rikihisa et al. Applicant urges that sine the combination of references do not teach or suggest every element of the claims, they cannot render the claims obvious.

Applicant's arguments filed February 23, 2004 have been fully considered but they are not persuasive. Rikihisa et al teach compositions of matter and articles of manufacture which such as a column, plastic dish, matrix or membrane preferably nitrocellulose containing an isolated outer membrane proteins of *E. chaffeensis or E. canis*. Rikihisa et al do not teach the use of a label indicates that the polypeptide can be used for the identification of *Ehrlichia* infection in a mammal. However, Waner et al teaches a label that indicates the use of the composition of matter or the article of manufacture (page 241, Figure 1). It would be *prima facie* obvious at the time the invention was made to add label as taught by Waner et al to the composition of matter or article of manufacture of Rikihisa et al because it is well known in the art to include packing material and a label to indicate the intended use of the composition of matter or article of manufacture. It should be noted that the printed matter on a label or package insert does not lend patentable weight as a limitation of the claimed product, absent a functional relationship between the label or package insert and the product, composition of matter or article of manufacture. See In re Haller 73 USPQ 403 (CCPA 1947), where it is held that application of printed matter to old article cannot render the article patentable. It is the Examiner's position that there is nothing on the record to suggest that the combination of references does not teach the claimed invention.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

9. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272–0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 5, 2004

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